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Remarks

The Office Action mailed 14 July 2003 has been received and reviewed. Claims 6, 38, 40-41, 50-52, 68, 70, 73, and 75 having been amended, the pending claims are claims 1-61 and 66-75. Claims 62-65 were previously canceled on 7 August 2002. Claims 53-65 and 71-75 were previously withdrawn from examination, such that claims 1-52 and 66-70 are presently under examination. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the amendments to claim 6 can be found in the specification at page 29, line 33, to page 30, lines 1-4.

Support for the amendments to claims 38-41 can be found in the specification at page 22, lines 8-9.

Information Disclosure Statement

Applicants' originally submitted Information Disclosure Statements on 27 February 2002. However, Applicants' Representatives note that copies of these 1449 forms have not been returned with subsequent actions from the U.S. Patent and Trademark Office. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-52, and 66-70 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that particular phrases were vague and indefinite, as the metes and bounds of these claims are unascertainable. This rejection is respectfully traversed.

The Examiner objected to the language "on average." Applicants respectfully submit that the language, "wherein the alkyl group of the alkyl-Y-containing side chain has a least 4 carbon atoms on average" (e.g., claim 1) is clear to one of skill in the art. One skilled in the art understands that a polymer is made from monomers. The claims recite "a vinyl polymer comprising ... alkyl-Y-containing side chains" (claim 1). That is, a vinyl polymer is derived from monomers wherein the monomers include alkyl-Y-containing side chains. Each monomer including an alkyl-Y-containing side chain includes an alkyl group on the side chain. The alkyl groups of the side chains of each individual monomer in the polymer may be of varying length, but the average number of carbon atoms on the side chain of the monomers that form the polymer is at least 4. Additionally, it is known in the art that many such monomers including side chains of varying lengths are available commercially as mixtures of compounds that would provide an "average number of carbons" or average chain length in the mixture. For example, submitted herewith as Exhibit A is product information for dimethyldioctadecylammonium chloride, which is a "a mixture of dialkyl dimethyl ammonium compounds, with carbon chain varying from C14 to C18, the C16 and C18 being the most abundant." Furthermore, a search of the U.S. patent database for the language of "carbon atoms on average" or "average chain length" in the claims of issued U.S. patents indicates over 300 hits. Thus, this is not an unusual or misunderstood term.

The Examiner objected to the phrase "sparingly soluble." Applicants' Representatives respectfully direct the Examiner's attention to the specification at page 7, lines 20-22 where the concept of solubility is discussed. Therein "soluble" vinyl polymers are those that form transparent homogenous solutions. This is defined in context with (and in contrast to) insoluble and sparingly soluble. Thus, read in context, one of skill in the art would know that polymers that are insoluble or sparingly soluble would not form a transparent homogenous solution.

Further, the Examiner alleged that the phrase "tissue" in claims 38, 40-41, and 68 is vague and indefinite, as it is unclear whether "tissue" refers to the paper product or to an in vivo organ. These claims have been amended to clarify that the invention is directed to mammalian tissue.

Further, the Examiner alleged that claim 6 is vague and indefinite as the claim language does not indicate what is the control for the reduction. It is respectfully submitted that one of skill in the art would understand the meaning of this claim, particularly in view of the discussion in Applicants' specification at page 17, lines 1-14. To clarify this claim, however, language from page 17, lines 8-9 has been added.

Finally, the Examiner alleged that the phrases "mask for the hair" and "composition for cushioning sores," in claims 44 and 45 (respectively) are vague and indefinite, as they are confusing due to the lack of definition for the phrase and meaning. It is respectfully submitted that these terms are well known terms and/or having meaning in the context of their use. Hair masks (i.e., hair masques) are used for nourishing and moisturizing hair, particularly damaged hair. Compositions for cushioning sores are used to cushion or mitigate further damage to sores (e.g., by providing lubricity, barrier, and moisturizing benefits).

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-45, 48-52, and 66-71 under 35 U.S.C. §103(a) as being unpatentable over Michaels (U.S. Patent No. 5,389,676) in view of Kernstock et al. (U.S. Patent No. 4,552,685). The Examiner also rejected claims 46-47 under 35 U.S.C. §103(a) as being unpatentable over Michaels (U.S. Patent No. 5,389,676) in view of Kernstock et al. (U.S. Patent No. 4,552,685) as applied to claims 1-45, 48-52, and 66-70 above, and further in view of Omura et al. (U.S. Patent Publication No. 2003/0064046). These rejections are respectfully traversed.

The Examiner cites Michaels for the disclosure of water-in-oil emulsions and Kernstock et al. for the disclosure of vinyl polymeric thickeners; however, there is no motivation

to combine these disclosures. Although both discuss the use of their compositions as shampoos, Michaels discloses both oil-in-water emulsions and water-in-oil emulsions. Furthermore, although the copolymeric thickeners of Kernstock et al. are insoluble in an aqueous liquid at a pH of less than about 2, there is no teaching or suggestion that such polymers could be used in an emulsion (whether it is an oil-in-water or a water-in-oil emulsion).

Kernstock et al. teach making the copolymeric thickeners in water while they are insoluble at low pH values; however, a reasonable interpretation appears that in use they are present in a soluble state. To support this interpretation, the Examiner is requested to note that the compositions of Kernstock et al. are solutions that are to remain clear after the copolymeric thickeners are added (see, e.g., column 4, lines 11-16). The Examiner is further directed to column 10, lines 18-24 where Kernstock et al. state: "The pH of the thickened, amphoteric surfactant compositions of this invention is suitably any pH at which the copolymer is soluble or sufficiently swollen to cause thickening without substantially reducing clarity." Hence, the implication is that solutions, as opposed to emulsions, are maintained.

Finally, with respect to claims 46 and 47, Omura et al. do not provide that which is missing from Michaels and Kernstock et al. Withdrawal of these rejections is respectfully requested.

Allegedly Duplicative Claims

The Examiner indicated that claims that only differ by the preamble are duplicative. Applicants' Representatives respectfully disagree. While certain claims (for example, those directed to a drug delivery composition, a moisturizing composition, a personal care composition, a mammalian tissue antiseptic, and a water-in-oil emulsion) may have the same claimed elements, this does not necessarily mean that they are of the same scope. These various types of compositions can have other components that make them different claimable subject matter. For example, a drug delivery composition would not necessarily have the same components as would a personal care composition, such as a shampoo, a bubble bath, or a nail

Amendment and Response

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Serial No.: 09/966,511

Confirmation No.: 4740

Filed: 28 September 2001

For: WATER-IN-OIL EMULSIONS WITH ETHYLENE OXIDE GROUPS, COMPOSITIONS, AND METHODS

polish. Applicants' Representatives respectfully direct the Examiner's attention to MPEP §2111.02 and point out that the preambles of the allegedly duplicative claims are more than merely statements of use or purpose.

Amendment and Response

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For: WATER-IN-OIL EMULSIONS WITH ETHYLENE OXIDE GROUPS, COMPOSITIONS, AND METHODS

Summary

It is respectfully submitted that the pending claims 1-61 and 66-75 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.10:

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By: Sue Dombroske

Name: Sue Dombroske



Substance

End Point : IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES
 Chemical Name : 1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride
 Common Name : Dimethyldioctadecylammonium chloride
 CAS Number : 107-64-2

Synonyms

Allquat 207	Ammonium, dimethyldioctadecyl-, chloride
Arosurf TA 100	Arquad 218-100
Arquad 218-100P	Arquad R 40
Cedequat TD 75	Dimethyldistearylammmonium chloride
Dioctadecyldimethylammonium chloride	Distearyldimethylammonium chloride
Di-n-octadecyldimethylammonium chloride	N,N-Dioctadecyl-N,N-dimethylammonium chloride
DSDMAC	Flotigam
Genamin DSAC	KD 83
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride	Praepagen
Q-D 86P	Quaternium 5
Sokalan 9200	Surfroyal DSAC
Talofloc	Varisoft 100
Verisoft 100	

Properties & Definitions

Molecular Formula : C₃₈H₈₀N.Cl
 Molecular Weight : 586.64
 Melting Point : 72-122C
 Boiling Point : 135C
 State : Solid
 Density : 840 kg/m³ (100% pure)
 Vapour Pressure : Low
 Water Solubility : 1 pg-2.5 mg/l at 25C
 General Comments : DSDMAC as isolated substance is not produced or used in a commercial range. Due to the use of tallow fatty acids for its manufacture, the product consists of a mixture of dialkyl dimethyl ammonium compounds, with carbon chain varying from C₁₄ to C₁₈, the C₁₆ and C₁₈ being the most abundant.

Overall Evaluation

NEEDS FURTHER WORK

SIDS INITIAL ASSESSMENT

Distearyldimethylammonium chloride (DSDMAC) is the major component in the technical product ditallowdimethylammonium chloride (DHTDMAC). In Germany, it is used as fabric softener, as additive in car washing agents and cosmetics, and to activate organic clays (bentonites). The use of DHTDMAC has strongly diminished in the last years in Germany.

DSDMAC is not readily biodegradable. Its removal in wastewater treatment plants (ca. 95%) is mainly due to adsorption onto sludge. The most sensitive environmental species to DSDMAC is the algae *Selenastrum capricornutum*: in river water tests, a 5 day-NOEC = 62 µg/L was determined, while in laboratory water, the 96 hour-NOEC was 6 µg/L.

There are inconsistent information on the volume of DSDMAC used in Germany. With a worst case volume of 780 t/y used in fabric softeners, the PEC was estimated to be 4.45 µg/L. According to the German producer only 60 t/y are used in fabric softeners.

The substance has low acute oral and dermal toxicity. The NOEL for repeated dose toxicity is 100 mg/kg/day. It produced negative results in an Ames test, and an in-vitro chromosomal aberration test showed no genotoxicity. DSDMAC has been detected in drinking water received from bank filtrate and surface water.

EXPOSURE

General discussion

DSDMAC as an isolated substance is not produced or used in a commercial range. The substance is the major component in dihydrogenated tallow dimethyl ammonium chloride, DHTDMAC, (acronym: ditallow dimethyl ammonium chloride, DTDMAC, contains some unsaturated bonds in the alkyl chains), which consists of a mixture of dialkyl dimethyl ammonium compounds with carbon chain length varying from C12 to C20. The alkyl chain length distribution in standard European products (e.g. praepagen WK, genamin DSAC, both containing approximately 65% DHTDMAC) is:

C12	max. 2%
C14	1 - 5%
C16	25 - 35%
C18	60 - 70% (DSDMAC)
C20	max. 2%

ENVIRONMENTAL EXPOSURE

DSDMAC is "not readily biodegradable".

General

During production in Germany, 150 kg of DSDMAC/y are emitted into the River Alz.

During use of the fabric softeners, more than 95% of the DHTDMAC adsorbs uniformly onto cloth, but it will be removed during the next wash. The substance is chemically stable under washing conditions. So the whole volume used for softeners (60 and 1380 t/y respectively) will be emitted into the household sewage. The same release path has to be expected for additives in cosmetics (50 t/y) and car washing products (107 t/y).

About 990 t/y are used to activate bentonites, where the natural cations are replaced by DHTDMAC to improve the swelling properties. 1/3 of these activated bentonites are used for the formulation of laquers, which are especially applied in the automobile industry. These laquers are normally applied in spray cabins. In the air laquer smog is remaining which is scrubbed with water. The aqueous phase is decanted from the laquer coagulate sludge and recirculated. The DHTDMAC adsorbed on the bentonite is partially solubilized by the washing water. At certain time however, the washing water has to be renewed and the waste water is released into the sewer.

There is no information available about releases during the use of activated bentonites as drilling muds in oil industry.

ENVIRONMENTAL FATE

There are different estimations of the "water solubility", the values are in the range from 1 µg/L to 2.5 mg/L. The "solubility" can be based on dispersion in water where the substance forms lamellar structures.

DSDMAC easily forms complexes with anionics such as alkylsulphonates or natural humic acids.

No data for the vapour pressure are available. Based on the molecular structure, an extremely low volatility is to be expected.

There are no experimental data for log Pow available. Because DSDMAC is a surface active substance, its estimation is not opportune as no conclusions on BCF or Koc can be drawn.

In two tests on *Lepomis macrochirus*, after 49 days BCFs of 13 and 32 respectively in the whole body and 94 and 260 respectively in the guts were estimated. These values indicate that there is a moderate to high bioaccumulation potential.

As found in several tests, DSDMAC is not readily biodegradable. A primary degradation was found after several days with an adapted inoculum, but mineralisation is very slow (e.g. 31.7% after 240 days). As shown in river water tests, degradation is occurring with a half-life in the range of several weeks.

A large part of removal in waste water treatment plants is due to adsorption onto sludge solids. In several tests